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88/046,658 APPLICATION NO.	05/28/99 FILING DATE	ADAI FIRST NAMED INVENTOR	ATTORNEY DOCKET NO. CARP-0057
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BURKE, J	EXAMINER
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ART UNIT 1642	PAPER NUMBER 18
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DATE MAILED:

05/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/846,658**

Applicant(s)  
**Adair et al**

Examiner  
**Julie E. Burke, (Reeves), Ph.D.**

Group Art Unit  
**1642**



☒ Responsive to communication(s) filed on 11/9/98; 11/16/98; 4/12/99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 24-31 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 24-31 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1642

### **DETAILED ACTION**

1. Claims 32-48 have been added and then canceled. Claims 24, 28-29 have been amended.
2. Applicants states that they wish to invoke an interference against an issued patent. Those remarks concerning the interference are held in abeyance until any allowable subject matter has been identified.
3. The text of those sections of Title 35, U.S.C. Code not included in this Office action can be found in a prior Office Action.

#### ***Specification***

4. The correction to the first line of the specification is noted.

#### ***Information Disclosure Statement***

5. Page 10 of paper no 3 filed 5/1/97 states that copy of the Information Disclosure Statement field in parent applications Ser no 08/303,569 and 07/743,929 have been submitted. The Examiner will correct the serial number on the Information Disclosure Statement to recite the instant application 08/846,658. The Information Disclosure Statements will be considered once the references have been submitted to the examiner.

#### ***Claim Rejections - 35 U.S.C. § 112***

6. Claim 24-31 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

Art Unit: 1642

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Claims 24 and 28 contain the limitation of “wherein each of said donor amino acids is adjacent to a CDR in the donor immunoglobulin sequence”. The Preliminary Amendment filed 5/1/97 states that page 6 lines 25-35 and Figures 3-4 of the specification supports this limitation. This is not persuasive. In Figure 3-4, the broader term “near” is not commensurate in scope with the more narrowly claimed term “adjacent”. On page 6, a series of potential substitutions are recited, of which only one, residue 49, is adjacent to any CDR. The specification does not provide support forth concept that only adjacent substitutions are envisaged, as encompassed by the newly added claim language “wherein each of said donor amino acids is adjacent to a CDR in the donor immunoglobulin sequence”. Further, the specification clearly teaches that a wide range of substitutions are contemplated, some of which are “adjacent” and some or which are only “near” the CDRs. Applicant is required to either point to where the specification provides support for the narrower phrase or to remove it from the claims.

b. The response set forth on page 3-4 has been considered carefully but is deemed not to be persuasive. The response argues that because the specification contains a listing of positions, one of which (1) is suggested in the alternative “48 and/or 49” and which (2) happens to be “adjacent” to a CDR, that Applicant is entitled to support for the broad limitation “each of the donor amino acids is adjacent to a CDR in the donor immunoglobulin”. This is not persuasive as the specification provides insufficient support for the claims as written.

Art Unit: 1642

c. The response concerning claims 27, 30 and 31, set forth on the first full paragraph of page 4 is sufficient.

7. The rejection of Claim 29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn in view of the amendment to the claims, taken in view of the teachings of the specification and the response set forth on page 4, second full paragraph.

***Claim Rejections - 35 U.S.C. § 102***

8. Claims 24-31 stand rejected under 35 U.S.C. 102(e) as being anticipated by Queen et al, (US patent No 5,585,089 which was filed Jun 7 1995 and has 102(e) priority back to at least 12/19/90).

a. The response set forth on page 4-5 has been considered carefully but is deemed not to be persuasive. The response correctly points out the obvious typographical error in the previous Office Action (12/28/90 should be 12/19/90). The response argues that the earliest Queen application do not teach that framework residues be replaced by donor must be outside both the Kabat and Chothia CDRs. This limitation is taught, for example, on page 9, lines 1-5 of

Art Unit: 1642

07/290,975 and page 13, lines 1-18 of 08/310,252 which has priority dates of 12/28/88 and 13 Feb 1989. Thus the rejection is made again and maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. No claims are allowed.

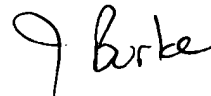
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, née Reeves, Ph.D, whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful,

Art Unit: 1642

the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,



Julie E. Burke, née Reeves, Ph.D.

Patent Examiner

(703) 308-7553

**JULIE BURKE  
PRIMARY EXAMINER**